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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,811	05/22/2001	David A. White	12553-009215	3520

7590

08/21/2003

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 08/21/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.



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20350 7590 07/16/2003

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Office Action Summary

Application No.

09/862,811

Applicant(s)

WHITE ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 18-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 18-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2003 and 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. This Office Action is responsive to the Amendment filed March 31, 2003. The Examiner acknowledges the amendments to the specification. Claims 12-13 and 18-38 are pending.

Drawings

2. The corrected or substitute drawings were received on March 31, 2003. These drawings are accepted by the Examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11-13, 18, 25-29 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. ('875) in view of Pomeranz ('609).

Makower et al. teach a catheter system for use with an imaging catheter. The catheter system includes a catheter body **10,102** including a proximal tubular portion **14,104**; an intermediate tubular portion **16,106** of a transitional material; and a distal tubular portion **18,108**. The intermediate tubular portion is disposed between the proximal and distal portions and has a higher flexural modulus than the distal tubular portion and a lower flexural modulus than the

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proximal portion. The proximal portion is formed of a plastic or polymer material including polyurethane, polyester or silicone. The intermediate portion is formed of a polymeric material including PEBAX which is a blend of polyurethane and nylon. Makower et al. teach all of the limitations of the claims except that the imaging catheter includes a drive cable.

Pomeranz teaches a guidewire imaging catheter including drive cable for rotating a work element of a imaging catheter. The guidewire imaging catheter is adapted to be used as an imaging catheter or as a means for positioning larger catheters.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use an imaging catheter including a drive cable similar to that of Pomeranz as the imaging catheter of a catheter system similar to that of Makower et al. in order to position the catheter body at a target tissue site.

5. Claims 19, 20, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. ('875) in view of Pomeranz ('609) as applied to claims 11 and 27 above, and further in view of Cottenceau et al. ('424). Makower et al., as modified by Pomeranz, teach all of the limitations of the claims except that the intermediate tubular portion is adhesively or thermally bonded with the proximal and distal tubular portions. Cottenceau et al. teach a catheter having three regions of variable rigidity. The catheter is formed by adhesively or thermally bonding an intermediate tubular portion **33** to a proximal tubular portion **31** and a distal tubular portion **35**, respectively. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to manufacture a catheter having three portions with variable longitudinal rigidity similar to that of Makower et al. as modified by

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Pomeranz by adhesively or thermally bonding the tubular portions coaxially in view of the teachings of Cottenceau et al. as an engineering design choice, simply substituting one known method of manufacturing such a catheter for another.

6. Claims 21-24 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. ('875) in view of Pomeranz ('609) as applied to claims 11 and 27 above, and further in view of Chow ('296). Makower et al., as modified by Pomeranz, teach all of the limitations of the claims except for the lengths of the intermediate tubular portion and the distal tubular portion. Chow teaches a catheter having longitudinal regions of changing flexibility. The catheter includes a distal portion B that has an intermediate tubular portion **42** having a length **L5** of 50 to 150 mm and a distal tubular portion **44** extending to a distal end of the catheter body having a length **L6** of about 200 to 300 mm. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that the lengths of the proximal, intermediate and distal portions of a catheter similar to that of Makower et al. as modified by Pomeranz could be selected within the range of those taught by Chow or otherwise as an engineering design choice to gradually alter the longitudinal flexibility of the catheter.

Response to Arguments

7. Applicant's arguments with respect to claims 11-13 and 18-38 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that the Office Action mailed January 27, 2003 fails to articulate basis for the combination set forth in the rejections under 35 USC 103(a). Applicant further contends that Makower et al. teach away from the

modification proposed by the Office Action where an arrangement that permits rotational control of the catheter system would be replaced with a drive cable for effecting rotation of a work element at the distal end of the catheter. Applicant argues that such a modification would change the principle of operation of Makower et al. which teach that the arrangement of the catheter system permits manual control over the distal portion of the catheter. This argument is not fully persuasive, but is moot in view of the new grounds of rejection set forth hereinabove.

Makower et al. teach a catheter device **100** including a catheter body **102** with proximal **104**, medial **106** and distal **108** segments of varying flexibility. The catheter body **102** may be manually rotated from the proximal end in order to control the position of an outlet aperture **134** at a distal portion of the catheter body. The outlet aperture **134** is adapted to direct a tissue penetrating element that extends through a working lumen **302** of the catheter to a desired target tissue site. Any of a variety of markers **180,182,186,188,310,340** may be provided on the catheter body that indicate the position of outlet aperture **134**. The catheter is further provided with an imaging lumen **300** through which an imaging catheter (e.g. an IVUS catheter) extends to locate the position of the marker and, ultimately, the position of the outlet aperture **134**.


Makower et al. does not limit the imaging catheter to any specific structure and does not teach that the imaging catheter is fixed longitudinally or rotationally within the imaging lumen. It appears that while the catheter body is manually controlled to determine the rotational position of the outlet aperture, the imaging catheter may be advanced and rotated within the imaging lumen in any fashion, including mechanically. In view of the foregoing, Applicant's arguments are not fully persuasive.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Primary Examiner
Art Unit 3736

CAM
July 10, 2003